

§ 184.1490

21 CFR Ch. I (4–1–04 Edition)

Dolah and S. B. Galloway, editors, National Marine Fisheries Service, U. S. Department of Commerce, pages 71–88, November, 1988, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (a)(2)(iii) of this section.

(3) In accordance with § 184.1(b)(2), the ingredient may be used in food only within the following specific limitations:

Category of food	Maximum level of use in food (as served)
Cookies, crackers, § 170.3(n)(1) of this chapter.	5.0 percent
Breads, rolls (white & dark), § 170.3(n)(1) of this chapter.	1.0 percent
Fruit pies, custard pies, § 170.3(n)(1) of this chapter.	7.0 percent
Cakes, § 170.3(n)(1) of this chapter ..	10.0 percent
Cereals, § 170.3(n)(4) of this chapter	4.0 percent
Fats, oils, § 170.3(n)(12) of this chapter, but not in infant formula.	20.0 percent
Yogurt, § 170.3(n)(31) of this chapter	4.0 percent
Cheese products, § 170.3(n)(5) of this chapter.	5.0 percent
Frozen dairy products, § 170.3(n)(20) of this chapter.	5.0 percent
Meat products, § 170.3(n)(29) of this chapter.	10.0 percent
Egg products, § 170.3(n)(11) of this chapter.	5.0 percent
Fish products, § 170.3(n)(13) of this chapter.	20.0 percent
Condiments, § 170.3(n)(8) of this chapter.	5.0 percent
Soup mixes, § 170.3(n)(40) of this chapter.	3.0 percent
Snack foods, § 170.3(n)(37) of this chapter.	5.0 percent
Nut products, § 170.3(n)(32) of this chapter.	5.0 percent
Gravies, sauces, § 170.3(n)(24) of this chapter.	5.0 percent

(b) *Hydrogenated and partially hydrogenated menhaden oils.* (1) Partially hydrogenated and hydrogenated menhaden oils are prepared by feeding hydrogen gas under pressure to a converter containing crude menhaden oil and a nickel catalyst. The reaction is begun at 150 °C and after 1 hour the temperature is raised to 180 °C until the desired degree of hydrogenation is reached. Hydrogenated menhaden oil is fully hydrogenated.

(2) Partially hydrogenated and hydrogenated menhaden oils meet the following specifications:

- (i) *Color.* Opaque white solid.
- (ii) *Odor.* Odorless.

(iii) *Saponification value.* Between 180 and 200.

(iv) *Iodine number.* Not more than 119 for partially hydrogenated menhaden oil and not more than 10 for fully hydrogenated menhaden oil.

(v) *Unsaponifiable matter.* Not more than 1.5 percent.–

(vi) *Free fatty acids.* Not more than 0.1 percent.

(vii) *Peroxide value.* Not more than 5 milliequivalents per kilogram of oil.

(viii) *Nickel.* Not more than 0.5 part per million.

(ix) *Mercury.* Not more than 0.5 part per million.

(x) *Arsenic (as As).* Not more than 0.1 part per million.

(xi) *Lead.* Not more than 0.1 part per million.

(3) Partially hydrogenated and hydrogenated menhaden oils are used as edible fats or oils, as defined in § 170.3(n)(12) of this chapter, in food at levels not to exceed current good manufacturing practice.

(4) If the fat or oil is fully hydrogenated, the name to be used on the label of a product containing it shall include the term “hydrogenated,” or if it is partially hydrogenated, the name shall include the term “partially hydrogenated,” in accordance with § 101.4(b)(14) of this chapter.

[62 FR 30756, June 5, 1997]

§ 184.1490 Methylparaben.

(a) Methylparaben is the chemical methyl *p*-hydroxybenzoate. It is produced by the methanol esterification of *p*-hydroxybenzoic acid in the presence of sulfuric acid, with subsequent distillation.

(b) The ingredient meets the specifications of the “Food Chemicals Codex,” 3d Ed. (1981), p. 199, which is incorporated by reference. Copies may be obtained from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or may be examined at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC 20408.

(c) The ingredient is used as an antimicrobial agent as defined in § 170.3(o)(2) of this chapter.

(d) The ingredient is used in food at levels not to exceed good manufacturing practices. Current good manufacturing practice results in a maximum level of 0.1 percent in food.

(e) Prior sanctions for this ingredient different from the uses established in this regulation do not exist or have been waived.

[42 FR 14653, Mar. 15, 1977, as amended at 49 FR 5612, Feb. 14, 1984]

§ 184.1498 Microparticulated protein product.

(a) Microparticulated protein product is prepared from egg whites or milk protein or a combination of egg whites and milk protein. These protein sources may be used alone or in combination with other safe and suitable ingredients to form the microparticulated product. The mixture of ingredients is high-shear heat processed to achieve a smooth and creamy texture similar to that of fat. Safe and suitable ingredients used in the preparation of the microparticulated protein product must be used in compliance with the limitations of the appropriate regulations in parts 172, 182, and 184 of this chapter.

(b) The ingredient is used in food in accordance with § 184.1(b)(2) at levels not to exceed current good manufacturing practice. The affirmation of the use of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following conditions of use:

(1) The ingredient is used in food as a thickener as defined in § 170.3(o)(28) of this chapter or as a texturizer as defined in § 170.3(o)(32) of this chapter.

(2) The ingredient is used in frozen dessert-type products except that the ingredient may not be used to replace the milk fat required in standardized frozen desserts.

(3) The name of the ingredient used in the ingredient statement on both bulk and packaged food must include the source of the protein (e.g., "microparticulated egg white protein"), followed by a parenthetical listing of each of the ingredients in the microparticulated protein product, in descending order of predominance. Microparticulated protein product

must be used in accordance with this requirement or its addition to food will be considered by FDA to constitute the use of an unapproved food additive (see § 184.1(b)(2)).

[55 FR 6391, Feb. 23, 1990]

§ 184.1505 Mono- and diglycerides.

(a) Mono- and diglycerides consist of a mixture of glyceryl mono- and diesters, and minor amounts of triesters, that are prepared from fats or oils or fat-forming acids that are derived from edible sources. The most prevalent fatty acids include lauric, linoleic, myristic, oleic, palmitic, and stearic. Mono- and diglycerides are manufactured by the reaction of glycerin with fatty acids or the reaction of glycerin with triglycerides in the presence of an alkaline catalyst. The products are further purified to obtain a mixture of glycerides, free fatty acids, and free glycerin that contains at least 90 percent-by-weight glycerides.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 201, which is incorporated by reference in accordance with 5 U.S.C. 552(a). Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or available for inspection at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC 20005.

(c) In accordance with § 184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used in food as a dough strengthener as defined in § 170.3(o)(6) of this chapter; an emulsifier and emulsifier salt as defined in § 170.3(o)(8) of this chapter; a flavoring agent and adjuvant as defined in § 170.3(o)(12) of this chapter; a formulation aid as defined in § 170.3(o)(14) of this chapter; a lubricant and release agent as defined in § 170.3(o)(18) of this chapter; a solvent and vehicle as defined in § 170.3(o)(27) of this chapter; a stabilizer and thickener as defined in § 170.3(o)(28) of this chapter; a surface-